IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2974**
	)	
	)	**1:20-MD-02974-LMM**
	)	
THIS DOCUMENT RELATES TO:	)	
	)	
ALISA ROBERE	)	**1:22-cv-01583-LMM**
PAULINE RICKARD	)	**1:21-cv-03861-LMM**
MELODY BRAXTON	)	**1:22-cv-00490-LMM**

TEVA'S MOTION TO CERTIFY ORDER FOR INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. 1292(b)

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Under 28 U.S.C. 1292(b), Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, LLC, and Teva Branded Pharmaceutical Products R&D, Inc. (collectively, "Teva") move the Court to certify its December 19, 2025 Order ("MSJ Order," *Rickard* ECF No. 137, *Robere* ECF No. 109, *Braxton* ECF No. 96), and stay trial court proceedings pending consideration of Teva's interlocutory appeal.

INTRODUCTION

A critical exception to the general rule against piecemeal appeals ensures that otherwise unappealable interlocutory orders that involve "a controlling question of law as to which there is substantial ground for difference of opinion" can be immediately appealed if doing so "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). The Court's MSJ Order holds that, in order to defeat a federal preemption defense, information in a 2015 FDA submission by Teva (Plaintiffs' Ex. 16[1]) and an expert report submitted in this litigation by Plaintiffs in 2025 (Teva Ex. R) can qualify as "newly acquired information" that would have permitted Teva to change its Paragard labeling without FDA approval before the Bellwether Plaintiffs' Paragard placements in 2011, 2012, and 2014. MSJ Order 9-13; *see* 21 C.F.R. § 314.3(b) (Changes Being Effected, or "CBE," regulation); *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. 299, 314-15 (2019) (discussing the CBE

[1] "Teva Ex. __" refers to the exhibits accompanying Teva's motion for summary judgment and reply in support thereof, ECF Nos. 42, 92; "Plaintiffs' Ex. __" refers to the exhibits accompanying Plaintiffs' summary judgment opposition, ECF No. 59. These record citations are to the documents filed on the *Rickard* docket (No. 1:21-cv-03861-LMM), unless otherwise noted.

regulation's exception to the preemptive effect of federal drug-labeling laws). In other words, the Court permitted later-conducted analyses to be used retroactively to establish "newly acquired information" at a previous time period on the ground that they could have or should have been conducted earlier.

That purely legal ruling amply satisfies all of the criteria for immediate appeal under Rule 1292(b). Indeed, another district court (and the Fifth Circuit) came to precisely that conclusion in a similar failure-to-warn case that Plaintiffs relied upon heavily in opposing summary judgment. *See In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 2022 WL 16923721, at *1 (E.D. La. Nov. 14, 2022) (certifying denial of summary judgment ruling holding that failure-to-warn claims were not preempted based on CBE regulation); *Hickey v. Hospira, Inc.*, 102 F.4th 748 (5th Cir. 2024) (vacating and remanding after granting interlocutory appeal).

First, the MSJ Order involves a "controlling question of law," 28 U.S.C. § 1292(b)—whether analyses can qualify as "newly acquired" under the CBE exception where the analyses were not actually "acquired" by the manufacturer and NDA holder before the relevant time period (*i.e.*, a plaintiff's ingestion or insertion of the prescription drug). 21 C.F.R. § 314.70(c)(6)(iii)(A); *id.* § 314.3(b). That question controls all of Plaintiffs' warning-based claims: if the answer is no, then Plaintiffs' claims are preempted and summary judgment in Teva's favor is required.

Second, the question is not only novel and important, but there is plainly

"substantial ground for a difference of opinion" as to its answer. 28 U.S.C. § 1292(b). Numerous district courts have addressed this issue in a variety of factual situations, and they have come to divergent views. *Compare, e.g.*, *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (rejecting argument that analyses manufacturer "could have" conducted earlier could amount to "newly acquired information" under CBE regulation), *and R.S.B. v. Merck & Co.*, 2022 WL 3927868, at *4 (E.D. Wis. Aug. 31, 2022) (similar), *with In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 508 F. Supp. 3d 71, 84-85 (E.D. La. 2020) (holding that information the defendant could have obtained by analyzing existing data and reports could satisfy the CBE "newly acquired information" standard). And while courts of appeals have addressed *some aspects* of what is necessary to satisfy the CBE regulation, *see Hickey*, 102 F.4th at 755-57 (holding that district courts must ensure that "newly acquired information" "reveal risks of a different type or greater severity or frequency than the risks" known by the defendant before FDA approval), no court of appeals has yet squarely addressed this critical temporal issue.

Third, an immediate appeal will "materially advance the termination" of not only Pauline Rickard's case currently scheduled for a bellwether trial in January, but Alisa Robere's case scheduled for a bellwether trial in March, Melody Braxton's case scheduled for a bellwether trial in May, and the approximately 3,600 other cases that are part of this MDL. 28 U.S.C. § 1292(b). In all of these cases, preemption is

dispositive of the plaintiffs' failure-to-warn claims. Whether the Eleventh Circuit agrees with or rejects this Court's holding, an immediate appeal will create much-needed clarity for the litigants and the Court, provide certainty that will enable more informed settlement discussions, and potentially avoid many months of work by the litigants and the court (and millions of dollars) spent in trial preparation and at trial. And if the Eleventh Circuit were to rule in Teva's favor regarding preemption of Plaintiffs' failure-to-warn claims and design-defect claims—both of which Teva intends to present if interlocutory review is granted[2]—an appeal would end this litigation entirely. At minimum, an immediate appeal could significantly narrow the claims and evidence to be heard by the jury at three upcoming bellwether trials, not to mention the thousands of other individual cases currently pending in the MDL.

Teva therefore requests that the Court certify its MSJ Order for immediate appeal and stay proceedings in the trial court while Teva's appeal is pending.

[2] Because "appellate jurisdiction applies to the *order* certified to the court of appeals," an appellate court may "review an entire order" upon granting interlocutory review, including issues not certified by the district court. *See Yamaha Motor Corp., U.S.A. v. Calhoun*, 516 U.S. 199, 205 (1996); *see, e.g.*, *Burlison v. McDonald's Corp.*, 455 F.3d 1242, 1248 (11th Cir. 2006) (considering merits of non-certified issue because "the courts may review all the matters in the district court's order"). While Teva disagrees with this Court's analysis of Plaintiffs' design-defect claims, that fact-bound analysis does not present the type of purely legal issue that would independently warrant an immediate appeal. A § 1292(b) motion need only show *one* question that warrants certification for interlocutory review to be appropriate, and so Teva focuses this submission on this Court's ruling regarding Plaintiffs' failure-to-warn claims, which amply satisfies the standard for interlocutory appeal.

QUESTION TO BE CERTIFIED FOR APPEAL

Whether information can retroactively qualify as "newly acquired" under the CBE exception where the information was not actually "acquired" by the drug manufacturing defendant before the relevant time period (*i.e.*, before a plaintiff's ingestion or insertion of the prescription drug).

ARGUMENT

I. The Decision Turns on a Controlling Question of Law.

As courts have recognized, "[w]hether federal law preempts the [plaintiffs'] claims certainly falls within the ambit of 28 U.S.C. § 1292(b)." *Spong v. Fid. Nat. Prop. & Cas. Ins. Co.*, 787 F.3d 296, 304 (5th Cir. 2015); *see also Merck*, 587 U.S. 315 (holding that preemptive effect of federal drug labeling requirements is an "issue of law"). That is particularly true with respect to the controlling question of law here. Whether the phrase "newly acquired information" in the CBE regulation can be interpreted to encompass analyses that were not actually "acquired" until after the relevant time period involves "the meaning of a statutory or constitutional provision, regulation, or common law doctrine"—the textbook definition of a "controlling question of law" suitable for § 1292(b) review. *McFarlin v. Conseco Serv., LLC*, 381 F.3d 1251, 1258 (11th Cir 2004).

Determining whether "newly acquired information" can be applied retroactively—and, relatedly, whether "newly acquired information" can encompass information that was not actually "acquired" but allegedly could have or should have

been—is "ultimately a question of [regulatory] interpretation," and thus "appropriate … for interlocutory review." *Heat Techs., Inc. v. Papierfabrik Aug. Koehler SE*, 2019 WL 1923663, at *2 (N.D. Ga. Apr. 18, 2019) (May, C.J.) (granting motion to certify). That question is "controlling" for essentially the same reasons that its resolution would materially advance the termination of the litigation. *See* Wright & Miller, 16 Federal Practice & Procedure § 3930 (3d ed.) (these criteria are "closely tied to" one another); *infra* pp. 13-18. If the Eleventh Circuit holds that "newly acquired information" cannot include analyses that were not actually "acquired" before a plaintiff used the defendant's product, then that answer controls the resolution of the Plaintiffs' failure-to-warn claims here: they are preempted by federal law, and summary judgment in Teva's favor is required. And given the purely legal nature of the question, resolution will have "general relevance to other cases" involving the CBE exception, including the thousands of other cases currently pending in this MDL. *McFarlin*, 381 F.3d at 1259.

Indeed, a district court (and the Fifth Circuit) certified a similar question for appeal regarding the proper interpretation of "newly acquired information" in the context of a failure-to-warn claim. *See Taxotere*, 2022 WL 16923721, at *5 (certifying question related to "interpretation of 'newly acquired information' as applied to § 505(b)(2) NDA holders"); *Hickey*, 102 F.4th 748 (vacating and remanding after granting interlocutory appeal). Accordingly, this case amply

satisfies the first prerequisite for interlocutory review.

II. There Is Substantial Ground for a Difference of Opinion.

There exists "a substantial difference of opinion on an issue" if "the issue is difficult and of first impression." *In re Suntrust Banks, Inc. ERISA Litig.*, 2011 WL 13824, at *2 (N.D. Ga. Jan. 3, 2011); *see also, e.g.*, *Doe 1 v. Red Roof Inns, Inc.*, 2020 WL 8092370, at *2 (N.D. Ga. Apr. 29, 2020). That is certainly the case here. The Eleventh Circuit has not squarely addressed whether later-developed analyses can retroactively establish "newly acquired information" permitting a labeling change under the CBE regulation on the ground that these analyses either could have or should have been performed earlier. *See* MSJ Order 11-12 (distinguishing prior holdings of other circuits and district courts on this basis and noting the "unique" nature of the issue).[3]

[3] Courts within the Eleventh Circuit have recited different standards, suggesting very different understandings about the appropriate interpretation of the CBE regulation and the preemptive effect of federal law. Most courts suggest that a plaintiff must establish that the manufacturer in fact "possessed" or knew the "newly acquired information." *Lyons v. Boehringer Ingelheim Pharms., Inc.*, 491 F. Supp. 3d 1350, 1363 (N.D. Ga. 2020) ("Plaintiff has not met her burden of showing that Defendant *possessed* newly acquired information…." (emphasis added)); *True v. AbbVie, Inc.*, 2025 WL 3560299, at *5 (N.D. Ga. Sept. 3, 2025) ("to avoid preemption, [the plaintiff] must plausibly allege that Defendants *possessed* newly acquired information" (emphasis added)); *Silverstein v. Boehringer Ingelheim Pharms., Inc.*, 2020 WL 6110909, at *11-*12 (S.D. Fla. Oct. 7, 2020) (plaintiff bears initial "burden of producing evidence that a drug manufacturer *acquired* new information after drug approval" (emphasis added)). Others have suggested that it may be sufficient for a plaintiff to point to information a manufacturer "should have had" but did not. *See Montalbano v. Ariad Pharms., Inc.*, 2015 WL 11198245, at *9 (S.D. Fla. Aug. 4, 2015); *McGee v. Boehringer Ingelheim Pharms., Inc.*, 2018 WL 1399237, at *4 (N.D. Ala. Mar. 20, 2018) ("The FDA's drug-labelling regulations do not preempt a state duty when a plaintiff can show that the manufacturer had *or should have had* newly-acquired information that it could and should have used to modify its label to comply with state-law expectations." (emphasis added)). The varying

Moreover, the answer to this question is not "so clear that the 'substantial ground for difference of opinion' requirement could not be met." *McFarlin*, 381 F.3d at 1258. On the one hand, some courts, sometimes relying on dicta from *Wyeth*, have held that *constructively* "acquired" information—*i.e.*, information that could have or should have been acquired earlier—could satisfy the CBE regulation and foreclose a federal preemption defense. MSJ Order 9-12; *see also In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 508 F. Supp. 3d at 84-85; *Newman v. McNeil Consumer Healthcare*, 2012 WL 39793, at *9-*11 (N.D. Ill. Jan. 9, 2012).

On the other hand, other courts have held that a manufacturer does not have "newly acquired information" merely because "it could have undertaken" an analysis of preexisting data. *R.S.B.*, 2022 WL 3927868, at *4; *see also Gayle*, 452 F. Supp. 3d at 88 (similar); *Holley v. Gilead Scis., Inc.*, 2023 WL 6390598, at *8 (N.D. Cal. Sept. 28, 2023) ("[A]sserting that a manufacturer could or should have done more studies—*i.e.*, that a manufacturer should have created the 'newly acquired information'—is insufficient to avoid preemption under the CBE regulation."); *Bueno v. Merck & Co.*, 746 F. Supp. 3d 853, 878 (S.D. Cal. 2024) (same); *In re Gardasil Prods. Liab. Litig.*, 770 F. Supp. 3d 893, 909 (W.D.N.C. 2025) (explaining that "evidence that [the manufacturer] did not *possess* until after the"

standards recited by courts within the Eleventh Circuit only highlight the clarity that immediate appellate review will provide, in this case and in others.

relevant time period "would not be relevant" in determining whether the manufacturer had "newly acquired information" (emphasis added)).[4]

The latter holdings are grounded in the CBE regulation's clear text: "newly acquired information" refers to information that has been in fact "acquired" by the manufacturer, not information that is theoretically available. *See* 21 C.F.R. § 314.70(c)(6)(iii) (allowing a manufacturer to unilaterally implement "[c]hanges in the labeling to reflect newly acquired information"). Indeed, FDA has described the CBE exception as "intended to apply only if the [manufacturer] *became aware* of newly discovered safety information that was appropriate for inclusion in the labeling." Proposed Rule, Supplemental Application Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2849 (Jan. 16, 2008) (describing the original CBE procedure from 1982, which is "essentially" identical to the modern CBE regulation) (emphasis added); *see also* Final Rule, Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49605 (Aug. 22, 2008) (envisioning that a manufacturer have the ability to "make a decision as to whether the requirements of [the CBE exception] are met" when "new information about a

[4] This Court distinguished *R.S.B.*, *Gayle*, *Holley*, and *In re Gardasil Products Liability Litigation* on the basis that they did not involve delay in discovering the relevant information "caused" by the manufacturer. *See* MSJ Order 11-12. But that factual distinction would be irrelevant if the Eleventh Circuit holds that "newly acquired information" cannot be applied retroactively.

drug comes to light").

This "narrow" application, *see* 73 Fed. Reg. at 49606; 73 Fed. Reg. at 2849-50, is also supported by the express purpose of the CBE regulation—to ensure that manufacturers use the CBE exception only for reasonable, *known* scientific risks, *see* 73 Fed. Red. at 2851 (emphasizing that the label should include "only '[k]nown hazards and not theoretical possibilities'"); 73 Fed. Reg. at 49605 ("This rule does not undermine a sponsor's responsibility to maintain its label—rather, it clarifies FDA's longstanding practice of requiring that sponsors must have sufficient evidence that the standards are met."). The CBE exception to the general rule that manufacturers cannot change the warnings on their labeling without prior FDA approval applies where there is "important *new information* about the safe use of a drug product" that must be "immediately conveyed" to users. 73 Fed. Reg. at 2850 (citations omitted); *see, e.g.*, *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 42 (1st Cir. 2015) (noting key examples of "newly acquired information" to include "new data from a clinical study evincing [the drug's] inefficacy"). It is not meant to encourage manufacturers to change labeling based on a hunch, much less allow manufacturers to be *deemed* to have newly acquired information that in fact they did not.

A contrary rule would also create incredibly tricky doctrinal and practical issues, as demonstrated by this case. The Court's analysis relied on (and effectively

applied retroactively to 2010) the 2015 Liu submission and the 2025 Kessler report—but both of those analyses included data that itself *post-dated* Plaintiffs' Paragard insertions (in 2011, 2012, and 2014). Dr. Liu, for example, undertook an analysis of adverse-event reports *through January 9, 2015*, the date the database search was performed. Plaintiffs' Ex. 16, Liu Submission at 11, 49. Similarly, Dr. Kessler's 2025 expert report analyzed the coding used by various Paragard manufactures to code complaints "from 1989 to the present." Teva Ex. R, Kessler Rep. at 7. Under the Court's MSJ Order, it is unclear whether the *entire* Liu and Kessler analyses are now fair game (even though they relied on data that could not possibly have been known before Plaintiffs' Paragard insertions). If so, then that would completely extinguish the CBE regulation's requirement that labels should reflect only "known" risks at any given time. And even if not—if Plaintiffs will be able to rely only on the analyses to the extent they were based on underlying data predating each Plaintiff's Paragard insertion, and will be required to prove that the CBE standard would still be satisfied if the underlying data were limited to that more circumscribed underlying dataset—then practical problems abound. For a litigation expert, like Dr. Kessler, carving up the underlying data in that way and tailoring testimony to a narrower data set might theoretically be possible, but that is unlikely to be the case for an analysis (like Dr. Liu's) that was completed a decade ago for purposes of a brief FDA submission and was not accompanied by a lengthy report.

Additionally, the Court's reliance on "unique" facts here—in particular, its agreement with Plaintiffs' theory that Teva's failure to sooner satisfy a 2006 FDA rule changing the format of physician-directed drug labeling justifies deeming Dr. Liu's 2015 analysis "newly acquired information" available in 2010—creates significant tension with other preemption doctrines. A failure-to-warn claim premised on Teva's failure to comply with the 2006 Physician Labeling Requirements Rule would be squarely barred by the doctrine of *Buckman* preemption, which recognizes that Congress forbid private plaintiffs from attempting to privately enforced duties owed by manufacturers to the FDA. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017); *Jacob v. Mentor Worldwide, LLC*, 40 F.4th 1329, 1336 (11th Cir. 2022). But the Court's holding here allows the Plaintiffs to circumvent this principle by using the regulatory violation as the reason why Plaintiffs' state-law failure-to-warn theory survives.

For all these reasons, the better interpretation is that "newly acquired information" must be information that was actually "acquired" at the relevant time, not information that could have or should have been acquired in a counterfactual world. At minimum, though, the existing split in authority and the reasonable arguments that exist on both sides underscore the "substantial ground for a difference of opinion" on this important, and controlling, question of law. 28 U.S.C. § 1292(b).

III. Immediate Appeal—and a Stay of Trial Proceedings—Would Materially Advance the Termination of Litigation in the Three Bellwether Cases and Thousands of Other Pending Cases in the MDL.

The "materially advance" prong is satisfied "where resolution of controlling questions could shorten the time, effort, and expense of the litigation." *McFarlin*, 381 F.3d at 1259 (citation omitted); Wright & Miller, 16 Federal Practice & Procedure § 3930 (standard satisfied when immediate appeal "involve[s] the possibility of … curtailing and simplifying pretrial or trial").

That standard is easily satisfied here. Crucially, interlocutory appeal and a stay of trial proceedings would advance the resolution of the *MDL as a whole*, well beyond these particular Bellwether Plaintiffs. As other courts have recognized, "because the Court's summary judgment ruling arises in the context of an MDL, the efficiencies to be gained by interlocutory appeal are particularly substantial." *In re General Motors Ignition Switch Litig.*, 427 F. Supp. 3d 374, 393 (S.D.N.Y. 2019); *see also, e.g.*, *In re 3M Combat Arms Earplug Products Liability Litig.*, 2022 WL 17853203, at *7 (N.D. Fla. Sept. 22, 2022) ("Given that this Order impacts all current and future cases in the MDL, as well as future trials, the Court finds that this Order 'involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from [it] may materially advance the ultimate termination of the litigation.'"); *In re Blue Cross Blue Shield*

Antitrust Litig., 2018 WL 3326850, at *6 (N.D. Ala. June 12, 2018); *Steering Comm. v. United States*, 6 F.3d 572, 576 (9th Cir. 1993).

In the closely analogous *Taxotere* case, for example, the court explained that "an immediate appeal of the Order will provide this Court with guidance as to the preemption analysis applicable to other cases against § 505(b)(2) defendants pending in this MDL" and, therefore, "'[t]he fact that the Court's ruling likely impacts a large number of claims further counsels in favor of appeal.'" 2022 WL 16923721, at *5 (quoting *General Motors Ignition Switch Litig.*, 427 F. Supp. 3d at 393). That reasoning fully applies here. Thus, even if "the Court would not have found the need for immediate appeal as pressing" if these issues had "arisen in the context of simpler, more conventional litigation," the MSJ Order's impact on the *thousands* of other cases in the MDL make § 1292(b) certification especially appropriate here. *General Motors Ignition Switch Litig.*, 427 F. Supp. 3d at 393. If "interlocutory appeal is appropriate only in 'big' cases," 16 Wright & Miller, Federal Practice & Procedure § 3929 (3d ed.), an MDL like this one certainly fits the bill.

Moreover, even as to the three Bellwether Plaintiffs' cases, if the Eleventh Circuit disagrees with this Court's interpretation of "newly acquired information," all of Plaintiffs' failure-to-warn claims are preempted. Accordingly, even *if* the Eleventh Circuit decides only that question and nothing else, that will significantly "'reduce the amount of litigation necessary on remand.'" *In re Blue Cross Blue*

Shield Antitrust Litig., 2018 WL 3326850, at *5 (citation omitted) (certifying question of law in MDL that was not case-dispositive, because "the court unhesitatingly finds that the reduction of any duplication of effort and expense materially advances the litigation"). Under this Court's MSJ Order, the design-defect claims remaining are exceedingly narrow: "Plaintiffs' allegations that Defendants could have and should have stayed with Dupont 2005 for the Paragard base material rather than switching to Dupont 20 and should have adhered to the bottom boundary of the allowable content of barium sulfate." MSJ Order 16. Conducting trials on those limited allegations would be far simpler and faster than conducting trials on Plaintiffs' sprawling failure-to-warn claims.

Additionally, interlocutory appeal on the failure-to-warn preemption issue "may help to advance settlement, a factor that courts have found significant in permitting interlocutory appeals to proceed." *Blue Cross Blue Shield Antirust Litig.*, 2018 WL 3326850, at *6 (citation omitted). The prospects of settlement would surely improve with a definitive answer from the Eleventh Circuit on the fate of Plaintiffs' failure-to-warn claims, particularly given the substantial gaps in proof that exist on the narrow design-defect claims that remain. *See infra* note 5. Indeed, "uncertainty about the status" of Plaintiffs' failure-to-warn claim[s] "may delay settlement …, and by doing so further protract the litigation"—and "[t]hat is enough to satisfy the 'may materially advance' clause of section 1292(b)." *Sterk v. Redbox*

Automated Retail, LLC, 672 F.3d 535, 536 (7th Cir. 2012) (citing, *e.g.*, *McFarlin*, 381 F.3d at 1259). These considerations are especially pronounced in MDLs, since "'the usual object of MDL management, especially with bellwether trials, is to incentivize rational settlements'" and "the vast majority of MDL cases are, in fact, resolved by settlement." *In re General Motors Ignition Switch Litig.*, 427 F. Supp. 3d 374, 393-94 (S.D.N.Y. 2019) (citation omitted).

Finally, while Teva does not argue that the Court's decision on the design-defect claims independently warrants certification, "interlocutory jurisdiction under section 1292(b) 'applies to the *order* certified to the court of appeals, and is not tied to the particular question formulated by the district court." *Joseph v. Bd. of Regents of the Univ. Sys. of Georgia*, 121 F.4th 855, 869 (11th Cir. 2024) (quoting *Yamaha Motor Corp., U.S.A. v. Calhoun*, 516 U.S. 199, 205 (1996)). The Eleventh Circuit therefore can—and often does—decide issues in the district court's order beyond the certified legal question. *See, e.g.*, *id.* (deciding non-certified question whether plaintiff stated a claim for retaliation); *accord Burlison v. McDonald's Corp.*, 455 F.3d 1242, 1248 (11th Cir. 2006); *Colonial Life & Acc. Ins. Co. v. Hartford Fire Ins. Co.*, 358 F.3d 1306, 1307 n.1 (11th Cir. 2004).

Here, if the Court grants this motion to certify under § 1292(b) and stays trial proceedings, Teva intends to ask the Eleventh Circuit to review the *entire* MSJ Order,

including the design-defect preemption issues.[5] And the Eleventh Circuit will likely review those issues as well, given their importance to thousands of pending claims in the MDL. If the Eleventh Circuit agrees with Teva on both issues, then judgment will be entered in Teva's favor, and there will be no need for any of the three upcoming bellwether trials. Accordingly, "an immediate appeal from the order may materially advance the ultimate termination of the litigation," 28 U.S.C. § 1292(b), with respect to *both* the failure-to-warn claims *and* the design-defect claims. *See, e.g.*, *Anderson Grp., LLC v. City of Saratoga Springs*, 2008 WL 2064969, at *7 (N.D.N.Y. May 13, 2008) (even if some claims were not controlling questions of

[5] Teva respectfully submits that the district court's design-defect analysis erred in numerous respects. The Court's ruling was premised on the notion that Teva could have complied with both state law and the Paragard NDA by using Dupont 2005 for the Paragard base rather than using Dupont 20, and by targeting a barium sulfate blend at the lower end of the 20-24% range that the Court understood the Paragard NDA to permit. MSJ Order 16-17. But those propositions are not supported by Plaintiffs' own proffered evidence, including the testimony of their materials expert, Dr. Mays. For instance, Dr. Mays did not opine that a Paragard with Dupont 2005 would have been safe. To the contrary, he opined that the use of *any* LDPE (including both Dupont 2005 and Dupont 20, Teva Ex. V, Mays Rep. at 65) without an antioxidant (which the NDA does not permit, Teva Ex. W, NDA at 8) was insufficient. Teva Ex. V, Mays Rep. at 11, 15-16, 20, 25-26, 27-28, 45, 88. He testified that if Teva had (as the evidence showed) continued to use Dupont 2005, that would have been "problematic" too. Plaintiffs' Ex. 37, Mays Rebuttal Rep. at 5. And he testified that continuing to use the NDA's FDA-approved design was "unacceptable." Teva Ex. V, Mays Rep. at 16. Likewise, Dr. Mays generally criticized the use of "high levels" of barium sulfate without suggesting that 23% was unsafe but 20% would have been safe. *Id.* at 12, 16, 42-45. And as even Dr. Mays recognizes, the NDA has expressly specified a 23% barium sulfate blend since 1993—which required a supplemental NDA and FDA approval for even a *1%* change from 22% to 23%. *Id.* at 70. The 20-24% range mentioned in the NDA and in Dr. Mays' report is the range permitted for the results of a molding powder ash content test that must be certified by the manufacturer. *Id.* at 43, 66, 69-70; Teva Ex. AA, NDA at 4. It would be inconsistent with the 23% NDA design specification for Teva to target a lower percentage of barium sulfate, even if the manufacturing process provides for a 20-24% acceptability ash content test range.

Teva acknowledges, however, that these analytical errors would not independently satisfy the § 1292(b) standard, and therefore does not brief them as an independent ground for certification.

law, interlocutory appeal may advance the termination of litigation because "the Circuit may elect to address the court's entire order on the parties' motions for summary judgment, as is within their power upon interlocutory review").

CONCLUSION

For the reasons discussed herein, Teva respectfully requests that the Court certify its Order for immediate review under 28 U.S.C. § 1292(b) and stay proceedings in the trial court while Teva's appeal is pending.

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CERTIFICATE OF COMPLIANCE

Pursuant to Local Rule 7.1(D), I hereby certify that I have prepared the foregoing in compliance with Local Rule 5.1 in Times New Roman 14-point font.

This 29th day of December, 2025.

/s/ Christopher D. Morris
Christopher D. Morris

CERTIFICATE OF SERVICE

I hereby certify that on this day I electronically filed the foregoing Motion with the Clerk of Court using the CM/ECF system, which will automatically send email notification of such filing to the attorneys of record.

This 29th day of December, 2025.

/s/ Christopher D. Morris
Christopher D. Morris